

### REMARKS

Claims 2-6, 8-17 and 23-44 are active in this application. Support for the amendment to Claim 3 is shown on page 9, first paragraph. Support for Claims 23-44 find support at Claims 2-6 an 8-17 as well as the specification as originally filed. No new matter is added by these amendments.

Applicants wish to thank Examiner Epps-Ford for the courteous discussion granted to the Applicants' undersigned representative on October 15, 2002. During this discussion, the amendments submitted herein concerning the percentage homology with SEQ ID NO:1, 3 or 5; or 16 was discussed.

The rejection of Claims 3-6, 9-12 and 14-17 under 35 U.S.C. § 112, first paragraph ("written description") is respectfully traversed.

The present claims are directed to specific DNA sequences; or DNA sequences which hybridize to those DNA under stringent conditions, which have 90% homology with the nucleotide sequences, and which encode a protein or a peptide with activity.

Applicants respectfully direct the Examiner's attention to Example 9 of the "Synopsis of Application of Written Description Guidelines", a copy of which is attached hereto. In Example 9, the Office has determined that a claim reciting an isolated nucleic acid that hybridizes under stringent conditions to a specific sequence and which has a specified activity is adequately described.

In the present application, the stringent conditions in the present claims is defined in the paragraph bridging pages 8-9. The percent homology is found on page 9. The activity associated with choline monooxygenase is described in the last paragraph on page 8. Therefore, the claims are adequately described by the specification as filed and as such withdrawal of this ground of rejection is requested.

The rejection of the claims under 35 U.S.C. § 102 over WO 98/30702, U.S. patent 6,310,271, Rathinasabapathi et al., and Nuccio et al. is believed to have been obviated by amendment.

The cited references do not describe a DNA which hybridizes SEQ ID NO: 1, 3 or 5 under stringent conditions, which has 90% homology with the nucleotide sequence shown in SEQ ID NO: 1, 3, or 5 and which encodes a protein having choline monooxygenase activity (see Claim 3); or which hybridizes to SEQ ID NO: 16 under stringent conditions, which has 90% homology with the nucleotide sequence shown in SEQ ID NO: 16 and which encodes a protein having single peptide activity (see Claim 9). At best the cited references describe a DNA which has 83% local similarity with SEQ ID NO: 1; or 87% identity with SEQ ID NO:16.

Therefore, withdrawal of the rejections under 35 U.S.C. § 102(b) or 102(e) is requested.

The objection of Claims 14-17 under 37 C.F.R. § 1.75(c) is obviated by amendment.

The objection to Claim 13 is believed to have been obviated by amendment and the arguments set forth above.

Applicants submit that the present application is now in condition for allowance.

Early notification of such allowance is kindly requested.

Respectfully submitted,

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IN THE CLAIMS

Please amend the claims as follows:

3. (Amended) A gene comprising the following DNA (c) or (d):

(c) a DNA comprising the nucleotide sequence shown in SEQ ID NO: 1, 3 or 5;

(d) a DNA which hybridizes to a DNA comprising the nucleotide sequence shown in SEQ ID NO: 1, 3 or 5 under stringent conditions, which has 90% homology with the nucleotide sequence shown in SEQ ID NO:1, 3 or 5, and which encodes a protein having choline monooxygenase activity.

9. (Amended) A gene comprising the following DNA (g) or (h):

(g) a DNA comprising the nucleotide sequence shown in SEQ ID NO: 16;

(h) a DNA which hybridizes to a DNA comprising the nucleotide sequence shown in SEQ ID NO: 16 under stringent conditions which has 90% homology with the nucleotide sequence shown in SEQ ID NO:16 and which encodes a protein having signal peptide activity.

18. (Canceled).

23-44. (New).

**SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION**  
**GUIDELINES**

**Contents**

Overview .....	2
Decision Trees	
Written Description Amended or New Claims or Claims	
Asserting the Benefit of an Earlier Filing Date ...	4
Original Claims .....	5
Example 1: Amended claims .....	3
Example 2: 35 USC 120 Priority .....	6
Example 2A: Essential element missing	
from original claim .....	8
Example 2B: A preferred element missing from original claim .....	10
Example 3: New claims .....	12
Example 4: Original claim .....	15
Example 5: Flow Diagrams .....	17

Example 6: Genes .....	20
Example 7: EST .....	23
Example 8: DNA Fragment Encoding a Full length	
Open Reading Frame (ORF) .....	26
Example 9: Hybridization .....	28
Example 10: Process Claim .....	31
Example 11: Allelic Variant .....	33
Example 12: Bioinformatics .....	40
Example 13: Protein Variant ... ..	43
Example 14: Product by Function .....	46
Example 15: Antisense .....	49
Example 16: Antibodies .....	52
Example 17: Genus-species with widely varying	
species.....	54
Example 18: Process claim where the novelty is in the	

method steps .....	58
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e.g. expression vectors, the necessary common attribute is the ORF (SEQ ID NO: 2).

Weighing all factors including (1) that the full length ORF (SEQ ID NO: 2) is disclosed and (2) that any substantial variability within the genus arises due to addition of elements that are not part of the inventor's particular contribution, taken in view of the level of knowledge and skill in the art, one skilled in the art would recognize from the disclosure that the applicant was in possession of the genus of DNAs that comprise SEQ ID NO: 2.

**Conclusion:** The written description requirement is satisfied.

**Example 9: Hybridization**

**Specification:** The specification discloses a single cDNA ( SEQ ID NO:1) which encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity. The specification includes an example wherein the complement of SEQ ID NO: 1 was used under highly stringent hybridization conditions (6XSSC and 65 degrees Celsius) for the isolation of nucleic acids that encode proteins that bind to dopamine receptor and stimulate adenylate cyclase activity. The hybridizing nucleic acids were not sequenced. They were expressed and several were shown to encode proteins that bind to a dopamine receptor and stimulate adenylate cyclase activity. These sequences may or may not be the same as SEQ ID NO: 1.

**Claim:**

An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1,



wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity.

**Analysis:**

A review of the full content of the specification indicates that the essential feature of the claimed invention is the isolated nucleic acid that hybridizes to SEQ ID NO: 1 under highly stringent conditions and encodes a protein with a specific function. The art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing.

The claim is drawn to a genus of nucleic acids all of which must hybridize with SEQ ID NO: 1 and must encode a protein with a specific activity.

The search of the prior art indicates that SEQ ID NO: 1 is novel and unobvious.

There is a single species disclosed (a molecule consisting of SEQ ID NO: 1) that is within the scope of the claimed genus.

There is actual reduction to practice of the disclosed species.

Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of

skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.

**Conclusion:** The claimed invention is adequately described.